

*IFW*

1648

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Nancy E. Yorke  
Name

Nancy E. Yorke  
Signature

Nov. 17, 2006  
Date



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Bryan, *et al.*

Serial No.: 10/573,330 - Case No.: 21500P

Art Unit:

1648

Filed: March 24, 2006

Examiner:

For: OPTIMIZED EXPRESSION OF HPV 45 L1 IN YEAST

Salimi, A.R.

Commissioner for Patents

Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This communication is in response to the outstanding Restriction Requirement mailed October 23, 2006, in the above-identified application, having a one-month period for response set to expire Friday, November 24, 2006. Reconsideration and allowance of the above-identified patent application are respectfully requested. Please credit any overpayment or charge any fee deficiency to Deposit Account No. 13-2755.

The Office Action states that the application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

- Group I, claims 1, 2, 6, 7 → drawn to nucleic acid molecule comprising nucleotide sequence of HPV45 L1.
- Group II, claims 3-5 → drawn to host cells
- Group III, claims 9-17 → drawn to virus-like particles of HPV-45, vaccines, methods of making and using.
- Group IV, claims 19-23 → drawn to multivalent vaccines.

US Appln. No.: 10/573,330  
US Filing Date: March 24, 2006  
Case No.: 21500P  
Page No.: 2

The Office Action further states that Applicant is required to elect a single one of these inventions to which the claims must be restricted.

By way of this response, Applicants respectfully traverse the Lack of Unity of Invention/Restriction Requirement set forth above. However, in order to be fully responsive, Applicants provisionally elect Group I, claims 1, 2, 6, and 7, without prejudice to the prosecution of the non-elected claims in related patent applications.

At the outset, Applicants respectfully point out that claim 8 was not mentioned as part of any of the specified groups, although it remains pending. Because claim 8 describes a host cell comprising the vector of claim 7 and other host cell claims are part of Group II, Applicants will assume that claim 8 was intended to be included as part of Group II for purposes of this response.

Under PCT Rule 13.1, inventions that are so linked as to form a single general inventive concept may be examined and prosecuted in a single case. As stated in the Office Action, if a group of claims share the same or corresponding special technical feature, one that identifies a contribution over the prior art, then those claims are so linked as to form a single general inventive concept. In the present case, Applicants traverse the restriction of Groups I and II because these groups clearly share the same or corresponding special technical feature which contributes over the prior art.

Group I contains claims to nucleic acid molecules comprising a sequence of nucleotides encoding HPV45 L1, said sequence codon-optimized for high expression in a yeast cell, and vectors comprising said nucleic acid molecules. Group II contains claims to host cells comprising said vectors. Each of the claims in the referenced groups describes a *yeast* codon-optimized nucleic acid molecule comprising a sequence of nucleotides encoding HPV45 L1, which is the special feature that is shared by the two groups. Prior to the present invention, nucleic acid molecules comprising the claimed elements were not known in the art. Contrary to the statement in the Office Action, which alleges that WO 01/14416 teaches codon-optimized polynucleotides encoding HPV45 L1 as taught in the present invention, the cited reference teaches polynucleotides codon-optimized for high expression in *human* cells. There are fundamental differences between polynucleotides codon-optimized for high-level expression in human cells and polynucleotides codon-optimized for high-level expression in yeast cells. Firstly, the "preferred" codons of human cells and yeast cells are different. Secondly, polynucleotides encoding HPV L1 that are codon-optimized for high-level expression in human cells are beneficial as DNA-based vaccines whereas polynucleotides that are codon-optimized for high-level expression in yeast cells are beneficial to produce HPV L1 protein *in vitro*, and therefore, beneficial as protein and/or VLP-based vaccines.

Moreover, because the same novel special technical feature is present in each of these claims, it would require no additional USPTO resources or present a burden on the USPTO to examine

US Appln. No.: 10/573,330  
US Filing Date: March 24, 2006  
Case No.: 21500P  
Page No.: 3

Group I and II claims in a single application. Thus, all claims in groups I and II share a special technical feature that provides a contribution over the prior art. Accordingly Applicants respectfully submit that it is not proper to restrict the claims of Groups I and II into separate applications based on PCT Rule 13.2.

Applicants also note that according to PCT Rule 13.4, it is permissible to include in the same application a reasonable number of dependent claims, claiming specific forms of an invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention. In the present case, claims 2-8, (Groups 1 and Group 2) which all depend on claim 1, present specific forms of the invention described in claim 1. As such, Applicants submit that it is not proper to restrict the claims in Groups I and II, pursuant to PCT Rule 13.2, as discussed in the previous paragraph, and pursuant to Rule 13.4, as discussed above.

Applicants, therefore, respectfully submit that Groups I and II (claims 1-8) should properly be examined in a single group in accordance with PCT Rules 13.2 and 13.4. As such, reconsideration and withdrawal of the requirement for restriction and/or regrouping of the claims, e.g., by combining Groups I- and II (claims 1-8) is respectfully requested.

Applicants assert all claims are in condition for allowance and a favorable action on the merits is earnestly solicited.

If the Examiner believes that a telephone conference would be of value, he is requested to call the undersigned attorney at the number listed below.

Respectfully submitted,

By

  
Alycia A. Finnegan  
Reg. No.: 48,878  
Attorney for Applicants

MERCK & CO., INC.  
P.O. Box 2000  
Rahway, NJ 07065-0907  
(732) 594-2583

Date: November 17, 2006